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In the Supreme Court

OF THE

United States

OCTOBER TERM, 1997

CRITIKON, INC.,
Cross-Petitioner,

v.

BECTON DICKINSON VASCULAR ACCESS, INC.,
Cross-Respondent.

On Conditional Cross-Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF IN OPPOSITION

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RULE 29.6 STATEMENT

In accordance with Rule 29.6, Sup.Ct.R., petitioner/cross-respondent Becton Dickinson Vascular Access, Inc. refers to page ii of the conditional cross-petition submitted by respondent/cross-petitioner Critikon, Inc.

TABLE OF CONTENTS

	Page
RULE 29.6 STATEMENT	i
TABLE OF AUTHORITIES	iv
SUMMARY OF ARGUMENT	1
STATEMENT OF THE CASE	2
I. Background	2
II. Critikon's Inequitable Conduct In Withholding McDonald	3
CORRECTION OF MISSTATEMENTS MADE IN CONDITIONAL CROSS-PETITION	6
I. Critikon Misrepresents The Evidence Relied Upon By The District Court	6
II. Critikon Misrepresents The Reasons For The Federal Circuit's Reversal	7
III. Critikon Misrepresents The Standard Applied By The Federal Circuit	9
REASONS FOR DENYING THE CONDITIONAL CROSS-PETITION	11
I. The Federal Circuit Properly Cited, Stated And Applied The Rule Of Law Set Forth In *FMC*	11
II. The Federal Circuit Properly Performed Its Appellate Function In Reversing The District Court's Findings On Materiality And Intent	11
A. The District Court Clearly Erred In Not Considering That McDonald Disclosed Lemieux's Point Of Novelty	12

Page

B. The District Court Clearly Erred In Not Considering Critikon's Failure To Report This Litigation During The Reissue Proceedings 13

C. The District Court Clearly Erred In Not Considering Objective Evidence Contradicting Critikon's "Explanation" For Withholding McDonald 14

CONCLUSION 15

TABLE OF AUTHORITIES

Page(s)

CASES

A.. Dick Co. v. *Burroughs Corp.*,
798 F.2d 1392 (Fed.Cir. 1986) 12-13

Anderson v. *City of Bessemer City*,
470 U.S. 564, 105 S. Ct. 1504 (1985) 6,8,12,14

Driscoll v. *Cebalo*,
731 F.2d 878 (Fed. Cir. 1984) 10,11

FMC Corp. v. *Manitowoc Co.*,
835 F.2d 1411 (Fed.Cir. 1987) 9,10,11

Gardco Mfg., Inc. v. *Herst Lighting Co.*, 820 F.2d
1209 (Fed.Cir. 1987) 12

Inwood Lab., Inc. v. *Ives Lab., Inc.*,
456 U.S. 844, 102 S. Ct. 2182 (1982) 15

Kingsdown Med. Consultants, Ltd. v. *Hollister*
Inc., 863 F.2d 867 (Fed.Cir. 1988), cert. denied,
490 U.S. 1067, 109 S. Ct. 2068 (1989) 9,10

LaBounty Mfg., Inc. v.
United States Int'l Trade Comm'n,
958 F.2d 1066 (Fed.Cir. 1992) 9

Molins PLC v. *Textron*,
48 F.3d 1172 (Fed.Cir. 1995) 9

United States v. *United States Gypsum*,
333 U.S. 364, 68 S. Ct. 525 (1948) 12,15

Page(s)

STATUTES

37 C.F.R. § 1.56(a) (1996) 5,13

35 U.S.C. § 251 ..... 3n.

RULES

Fed. R. Civ. P. 52(a) 11

Sup. Ct. R. 29.6 i

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BRIEF IN OPPOSITION

SUMMARY OF ARGUMENT

This is not a case where a court of appeals has reversed a district court's findings "simply because it is convinced it would have decided the case differently" (Cross-Petition at 9). This is not a case where a court of appeals is "wrongly substituting its own interpretation of the facts" (*Id.* at 10). This is not a case where the court of appeals "rejected the district court's findings on credibility, and . . . improperly relied exclusively on . . . thoroughly discredited testimony" (*id.* at 5-6) "without showing any deference at all to the district court's findings" (*Id.* at 10).

This is a case where the evidence of record clearly establishes that the Lemieux patent was procured through inequitable conduct, but the District Court's findings were erroneously based on an incomplete consideration of that evidence. The District Court overlooked evidence of record demonstrating that the withheld McDonald patent disclosed the features considered by the patent examiner to be the "point of novelty" of the Lemieux patent. The District Court also misapprehended the scope of a patent applicant's duty under 37 C.F.R. § 1.56(a) and thus overlooked cross-petitioner Critikon's unexplained failure to report this litigation — and the charge of inequitable conduct based on Critikon's failure to disclose the McDonald patent — during proceedings to reissue the Lemieux patent.

The Federal Circuit properly performed its appellate function in correcting the District Court's erroneous views of materiality and intent and in applying the proper standards to the undisputed facts of record. For all these reasons, as set forth more fully below, the conditional cross-petition should be denied.

STATEMENT OF THE CASE

I. Background

Intravenous catheters consist of thin plastic tubes that are inserted into veins so that fluids can be introduced into the body. A hub at one end of the catheter tube allows connection to the fluid delivery system. To enable insertion into a vein, catheters are mounted over introducer needles (3a, 21a).

The Lemieux patent is directed to safety catheters. Safety catheters have a "needle guard" that is positioned over the tip of the introducer needle when the needle is withdrawn from the catheter. The needle guard protects health care workers from accidental needle sticks (3a, 21a).

Early safety catheter designs required health care workers to position the needle guard over the needle tip by manually sliding it along the needle as the needle is withdrawn from

the catheter. Michael McDonald, a paramedic in Chicago, recognized the danger inherent in the manual positioning step and invented a technique that automatically positions the needle guard over the needle tip. The heart of his invention was a "retaining" or locking means that: (a) holds the needle guard and catheter hub together while the needle is in the catheter and (b) disengages the guard from the hub only after the needle tip is safely withdrawn from the catheter into the guard (6a).

The safety catheter described in the Lemieux patent uses the same retaining means technique that McDonald invented. Like McDonald, Lemieux automatically positions the needle guard over the tip by using a retaining means that holds the needle guard together with the catheter hub while the needle is withdrawn, and then disengages the needle guard from the catheter hub (23a-24a).

II. Critikon's Inequitable Conduct In Withholding McDonald

As the Federal Circuit's August 12, 1997 Opinion in this case clearly explains, Critikon engaged in inequitable conduct in withholding the McDonald patent during the original Lemieux prosecution and during proceedings to "reissue"* that patent.

First, Critikon not only knew that the retaining means used to automatically position the needle guard was the "point of novelty" of the Lemieux device during prosecution; Critikon specifically relied on that point to obtain allowance:

> Critikon knew that the examiner considered the retaining means a point of novelty of the Lemieux patent. The

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* A patentee may seek to have a patent "reissued" by the Patent and Trademark Office to correct certain defects that may render the patent wholly or partly invalid. 35 U.S.C. § 251. Like the original prosecution process, a reissue procedure is *ex parte* and places the same duty on the applicant to disclose all known information material to patentability (11a-12a). The reissue proceedings for the Lemieux patent concluded seven months after Critikon brought this action (20a).

> examiner was in direct communication with Critikon and reiterated on at least two occasions the importance of the "retaining means" as a point of novelty in the application. During the course of prosecution of the original Lemieux patent, the examiner twice rejected the application's independent claims that did not call for a means for retaining the needle guard together with the catheter hub. Both times, the examiner stated that those claims "lack the structure at the point of novelty to achieve the intended result and are therefore incomplete," and suggested that they be amended to include retaining means for holding the needle guard within the catheter hub until the needle guard was engaged in place over the needle tip (7a).
>
> * * *
>
> . . . Mr. Colletti [Critikon's patent attorney who prosecuted the Lemieux patents] relied on the novelty of the "retaining means" and the automatic positioning of the protective housing in his arguments to gain allowance of the patent application (11a).

Second, Critikon knew that, unlike any other art submitted to the Examiner, the McDonald patent disclosed the retaining means:

> The use of the "retaining means" to achieve automatic positioning is disclosed only in the uncited McDonald patent; it is not disclosed in any other prior art considered by the examiner. . . .
>
> . . . Mr. Fischell [Becton Dickinson's expert] indicated that the key features of McDonald were the automatic positioning and the "retaining means." Mr. Colletti reflected this position, and Critikon's knowledge thereof, when he testified that he could not recall any prior art considered by the examiner who allowed the original Lemieux patent that describes a catheter device with the "retaining means" (10a).

Third, Critikon withheld the McDonald patent with intent to deceive the Examiner:

> Critikon was intimately familiar with the McDonald patent. Both of Critikon's patent counsel who were involved in the prosecution of the Lemieux patents, Mr. Colletti and Mr. York, had reviewed the McDonald patent in detail. On appeal, Critikon argues that Mr. Colletti believed that the reference was not material and that Mr. York had no recollection of the patent. However, at one point Mr. York reviewed the McDonald patent and in handwritten annotations opined that all the claims, except those including the "retaining means," were invalid. Further, there is evidence that he passed these notes on to Mr. Colletti, who cited the McDonald patent to the PTO in several other patent proceedings. If that were not sufficient to infer intent to mislead or deceive, the record indicates that Critikon's counsel was repeatedly confronted with the McDonald patent and its significance over the course of the litigation, which substantially overlapped the Lemieux reissue proceedings (7a).

Fourth, Critikon failed to disclose the pendency of this litigation — and the charge of inequitable conduct — during the reissue proceeding:

> A patent applicant's duty to disclose is not limited to disclosing prior art. A patent applicant must disclose any material information to the PTO. 37 C.F.R. § 1.56(a) (1996). There seems little doubt that the litigation involving the patent in question would be relevant to its reissue proceeding. According to the Manual of Patent Examining Procedure, relevant litigation includes the defenses raised against validity of the patent, or charges of fraud or inequitable conduct in the litigation, which would normally be material to the reissue application. MPEP 2001.06(c) (1994) (11a-12a).

CORRECTION OF MISSTATEMENTS MADE IN CONDITIONAL CROSS-PETITION

In addition to its incomplete statement of the case, the conditional cross-petition includes many serious misstatements. For example, in asserting that the District Court's opinion should not be reversed, Critikon improperly attempts to "insulate [the District Court's] findings from review by denominating them credibility determinations." *Anderson* v. *City of Bessemer City,* 470 U.S. 564, 575, 105 S.Ct. 1504 (1985). In criticizing the Federal Circuit's judgment, Critikon fails to mention an important basis for that judgment: the District Court did not consider Critikon's failure to report this litigation — and the charge of inequitable conduct — to the Patent and Trademark Office while attempting to "reissue" the Lemieux patent. Critikon also grossly misrepresents the legal standard stated and applied by the Federal Circuit.

I. Critikon Misrepresents The Evidence Relied Upon By The District Court

Critikon suggests that this trial presented a great contest of credibility on the issue of inequitable conduct between Critikon's *"witnesses"* (Cross-Petition at 4; emphasis added) and Becton Dickinson's technical expert, Mr. Fischell. The facts tell quite a different story.

Critikon did not present *any* witness at trial on the issue of inequitable conduct and offered no testimony on the McDonald patent.* The only trial testimony on this issue was that of Mr. Fischell, who testified that — unlike any prior art considered by the Examiner — McDonald disclosed Lemieux's point of novelty. That testimony was confirmed by Mr. Colletti's deposition testimony that he could not recall any prior art considered by the Examiner that disclosed those features. Critikon's technical expert, Mr. Vaillancourt,

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* Critikon objected to any cross-examination of its expert Mr. Vaillancourt on McDonald.

gave no testimony either challenging Mr. Fischell's conclusion or supporting Mr. Colletti's unfounded, conclusory characterization of the McDonald patent as "cumulative" of prior-art considered by the Examiner. Given the fact that Mr. Fischell's testimony concerning the materiality of the McDonald patent went unchallenged at trial, Critikon's current attempts to discredit him ring quite hollow.

II. Critikon Misrepresents The Reasons For The Federal Circuit's Reversal

Critikon claims that the Federal Circuit disregarded unspecified "credibility determinations" and "wrongly substituted its own interpretation of the facts" in reversing the District Court (Cross-Petition at 5-6, 10 and 11) is wrong. The District Court was reversed because it: (a) did not consider that the McDonald patent disclosed key features claimed by Lemieux; (b) did not consider evidence that Critikon failed to report this litigation during the reissue proceedings and (c) did not consider objective evidence that contradicted the "explanation" given by Mr. Yorks and Mr. Colletti for withholding the McDonald patent.

With respect to the District Court's error concerning the materiality of the McDonald patent, the Federal Circuit concluded that:

> The court apparently failed to recognize that although overall the Lemieux device may be substantially different from McDonald, the McDonald patent teaches two features, which the examiner considered central in the prosecution of the Lemieux patents (10a).

In reviewing the evidence concerning those features not considered by the District Court, the Federal Circuit found probative of McDonald's materiality: (a) the fact that the Examiner considered those features to be Lemieux's "point of novelty" (7a and 10a); (b) the fact that Mr. Colletti relied on those features to gain allowance of Lemieux's application (7a and 11a); and (c) Mr. Fischell's testimony that the

McDonald patent *alone* disclosed those features — a position "reflected" by Mr. Colletti's inability to recall any prior art considered by the Examiner that disclosed those features (10a-11a).

The Federal Circuit concluded that it was even more important (5a and 12a) that the District Court had erred by failing to consider both this litigation's materiality to the reissue proceedings (11a-12a) and Critikon's unexplained failure to report this litigation to the Patent and Trademark Office (8a). Plainly, no "credibility determinations" were rejected nor facts found *de novo* by the Federal Circuit's consideration of that evidence.

Finally, the Federal Circuit concluded that the District Court clearly erred in not considering objective evidence contradicting Mr. Yorks' and Mr. Colletti's "explanation" that they had withheld the McDonald patent because it was "cumulative" of prior art already before the patent Examiner (8a). That objective evidence included: (a) their intimate familiarity with the McDonald patent (7a); (b) the fact that they specifically relied on features disclosed in the McDonald patent to gain issuance of the Lemieux patent (7a-8a and 11a); (c) the fact that no prior art before the Examiner disclosed those features (10a-11a), and (d) the fact that Mr. Colletti "was repeatedly confronted with the McDonald patent and its significance over the course of the litigation, which substantially overlapped with the Lemieux reissue proceedings" (7a).

Contrary to Critikon's assertions, the Federal Circuit did not disregard the District Court's role as fact finder. Even assuming that the District Court had an opportunity to assess Mr. Yorks' and Mr. Colletti's "demeanor and tone of voice" (Cross-Petition at 11) — which it did not — where objective evidence contradicts a witness' story "the court of appeals may well find clear error even in a finding purportedly based on a credibility determination." *Anderson, supra* 470 U.S. at 575. This is particularly so in a case such as this where "the record does not reveal a single instance where Mr. Yorks or Mr. Colletti provided a good faith explanation"

for withholding the McDonald patent (8a) — and Critikon did not bring Mr. Yorks and Mr. Colletti to trial to provide one.

III. Critikon Misrepresents The Standard Applied By The Federal Circuit

Finally, Critikon makes several misrepresentations concerning the legal standard stated and applied by the Federal Circuit.

In *Kingsdown Med. Consultants, Ltd.* v. *Hollister Inc.*, 863 F.2d 867 (Fed.Cir. 1988), *cert. denied*, 490 U.S. 1067, 109 S.Ct. 2068 (1989) the Federal Circuit resolved "conflicting precedent regarding whether a finding of gross negligence *compels* a finding of intent to deceive" *Molins PLC* v. *Textron*, 48 F.3d 1172, 1181 n.11 (Fed.Cir. 1995) (emphasis added). *Kingsdown* adopted the holding in *FMC Corp.* v. *Manitowoc Co.*, 835 F.2d 1411 (Fed.Cir. 1987) that:

> an applicant who *knew or should have known* of the art or information, and of its materiality, is *not automatically* precluded thereby from an effort to convince the fact finder that . . . an inference of an intent to mislead is not warranted (*Id.* at 1416; emphasis added).

FMC nevertheless cautioned that:

> a patentee facing a high level of materiality and clear proof that it *knew or should have known* of that materiality, can expect to find it difficult to establish "subjective good faith" sufficient to prevent the drawing of an inference of intent to mislead. A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice in such circumstances (*Id.;* emphasis added).

See also LaBounty Mfg., Inc. v. *United States Int'l Trade Comm'n*, 958 F.2d 1066, 1076 (Fed.Cir. 1992).

Critikon first incorrectly states that *Kingsdown* rejected the rule that "wrongful intent *can* be found where an applicant 'should have known' that a reference was material"

(Cross-Petition at 6; emphasis added). That is not so. *Kingsdown* rejected the proposition set forth in *Driscoll* v. *Cebalo*, 731 F.2d 878 (Fed.Cir. 1984) that intent is *compelled* by a such a finding.

Second, Critikon incorrectly claims that the Federal Circuit "reverted to" and "resurrected" the *Driscoll* standard. On the contrary, the Federal Circuit correctly stated that:

> intent *may* be inferred where a patent applicant knew or should have known, that withheld information would be material to the PTO's consideration of the patent application (6a; emphasis added);

Indeed, the Federal Circuit applied *FMC's* cautionary note to Critikon: "Given the materiality and the failure at any point to offer a good faith explanation of the pattern of nondisclosure, an intent to mislead may be inferred" (9a and 12a). Indeed, "[a] relatively high degree of intent may be inferred" (6a).

Moreover, Critikon's claim that the Federal Circuit misapplied the law is belied by the fact that within weeks of entry of the Federal Circuit's opinion, Ethicon, Inc., an affiliate of Critikon at Johnson & Johnson, cited and quoted the Federal Circuit's opinion in this case *five times* in opposing a motion to strike an inequitable conduct defense *it* had raised. Indeed, Critikon's affiliate specifically relied on the Federal Circuit's application of the *FMC* standard:

> To overcome the inference of intentional deception, U.S. Surgical's witnesses must come forward with a "good faith explanation" sufficient to render the circumstances innocent. A "mere denial . . . will not suffice."*

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* *Ethicon, Inc.* v. *United States Surgical Corp.*, D.Conn., Civil No. B 89-386 (RNC) (August 27, 1997, Docket No. 788). Redacted portions of that memorandum are reproduced at 1a-6a, attached hereto.

REASONS FOR DENYING THE CONDITIONAL CROSS-PETITION

I. The Federal Circuit Properly Cited, Stated And Applied The Rule Of Law Set Forth In *FMC*

As discussed above, Critikon grossly misstates the legal standard used by the Federal Circuit in reversing the District Court's finding on intent. The Federal Circuit cited, stated and applied to the facts of record the standard of *FMC, supra:* that "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality" cannot prevent the drawing of an inference of intent to mislead by a mere denial of that intent. *FMC, supra* at 1416. The Federal Circuit's opinion neither stated or applied the proposition set forth in *Driscoll* that gross negligence compels a finding of inequitable conduct.

The entire basis for Critikon's first question presented is thus the Federal Circuit's *citation* of *Driscoll.* The fact that *Driscoll* does not stand for the accepted rule of law stated and applied by the Federal Circuit does not in any way undermine the Federal Circuit's opinion. Critikon's request that this Court consider the first question presented is meritless and should be denied.

II. The Federal Circuit Properly Performed Its Appellate Function In Reversing The District Court's Findings On Materiality And Intent

With respect to Critikon's second question presented, the Federal Circuit properly performed its appellate function in reversing the District Court's findings on materiality and intent. There is no basis for Critikon's claim that the "court below wholly disregarded the appropriate standard of review that governs all of the United States Courts of Appeals" (Cross-Petition at 12).

Rule 52(a), Fed.R.Civ.P., requires federal courts of appeal to accept findings of fact unless they are "clearly erroneous." A finding of fact is clearly erroneous when an appellate court "on the entire evidence is left with the definite and firm

conviction that a mistake has been committed." *Anderson, supra,* 470 U.S. at 573; *United States* v. *United States Gypsum,* 333 U.S. 364, 395, 68 S.Ct. 525 (1948). The Federal Circuit fully appreciated this standard:

> the court's ultimate determination is reviewed for abuse of discretion; the subsidiary factual questions are reviewed for clear error and are not to be disturbed unless we have a definite and firm conviction that a mistake has been committed. (5a; citation omitted).

A. The District Court Clearly Erred In Not Considering That McDonald Disclosed Lemieux's Point Of Novelty

The facts of record on appeal demonstrate that the McDonald patent disclosed features that the Examiner considered to be the "point of novelty" of Lemieux's invention. The evidence also showed that Critikon's attorneys relied on those specific features to gain allowance of the Lemieux patent and that no prior art before the examiner disclosed those features. The District Court made no findings to the contrary — let alone contrary findings based on credibility determinations.

Unable to dispute that evidence, Critikon's post-trial submissions urged the District Court to "consider the entirety of the subject matter claimed by Lemieux, and [not] a flawed 'point of novelty' approach." The District Court accepted that analysis, reviewed the evidence accordingly, and was persuaded that the McDonald patent "teaches a *device* that is substantially different than that contemplated by the Lemieux patents" (52a; emphasis added).

The definition of materiality, however, is not limited to a comparison of the claimed invention as a whole. "[I]nformation is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Gardco Mfg., Inc.* v. *Herst Lighting Co.,* 820 F.2d 1209, 1214 (Fed.Cir. 1987) (no error in "high-lighting the similarities between the fixtures"); *A.B. Dick Co.* v. *Burroughs Corp.,*

798 F.2d 1392, 1397 (Fed.Cir. 1986) (the reference did not disclose the "object" of the invention but did describe "the most important part of the system"). "[A]pplicants have a duty to disclose to the PTO information of which they are aware which is material to the examination of the application." 37 C.F.R § 1.56(a) (see 5a, 9a and 11a).

The District Court thus clearly erred by not considering the facts of record which established that the McDonald patent disclosed the point of novelty of the Lemieux patent. In considering the undisputed facts of record, the Federal Circuit did not reject any "credibility findings" or decide any factual issues *de novo.* On the contrary, the Federal Circuit's opinion gives guidance to trial courts by correcting the District Court's overly narrow view of materiality ("[a] device that operates differently . . . may nonetheless have relevant features" (11a)) and by illustrating the application of that proper standard to the undisputed facts of record.

B. The District Court Clearly Erred In Not Considering Critikon's Failure To Report This Litigation During The Reissue Proceedings

The District Court also clearly erred in not considering evidence concerning Critikon's failure to report the existence of this litigation (and the charge of inequitable conduct for failure to disclose the McDonald patent) to the Patent and Trademark Office during the proceedings to reissue the Lemieux patent. It is clear that Critikon's duty was not limited to disclosing prior art (37 C.F.R. § 1.56(a)) and it is self-evident that "litigation involving the patent in question would be relevant to the reissue proceeding" (11a). Again, the District Court made no finding to the contrary — let alone a finding based on credibility determinations.

Contrary to Critikon's suggestions, the Federal Circuit neither substituted "its own interpretation of the facts" (Cross-Petition at 10) nor decided any factual issues *de novo* in considering the complete *lack* of evidence of any good faith explanation for Critikon's failure to report this litigation to the Patent and Trademark Office. Again, the Federal

Circuit's opinion gives guidance to trial courts by correcting the District Court's overly narrow focus on Critikon's failure to disclose prior art — rather than "any material information" (11a).

C. The District Court Clearly Erred In Not Considering Objective Evidence Contradicting Critikon's "Explanation" For Withholding McDonald

Finally, the District Court clearly erred in accepting Critikon's "explanation" of why its attorneys withheld the McDonald patent from the Patent and Trademark Office. The record on appeal fully supports the Federal Circuit's reversal of the inference of good faith found by the District Court. The deposition "explanation" relied upon by the District Court is conclusory, unsupported by any corroborating evidence and directly contradicted by all the objective evidence on point.

Mr. Yorks gave no explanation. Mr. Colletti's conclusory claim that the McDonald patent was cumulative of other unidentified prior art was refuted by his admission that he could not recall any prior art *considered by the Examiner* that disclosed the retaining means used in the Lemieux device and by Critikon's refusal to permit Mr. Colletti to identify that "other" prior art. Moreover, that preposterous explanation is not due any greater deference because the District Court's did not assess Mr. Yorks' and Mr. Colletti's "demeanor" or "tone of voice" (Cross-Petition at 11). Critikon could have brought Mr. Yorks and Mr. Colletti and to testify at trial — but chose not to.

The Federal Circuit's detailed reasoning concerning the "explanation" given by Mr. Yorks and Mr. Colletti is a textbook implementation this Court's guidance in *Anderson,* 470 U.S. at 575:

> Documents or objective evidence may contradict the witness' story; or the story itself may be so internally inconsistent or implausible on its face that a reasonable factfinder would not credit it. Where such factors are present, the court of appeals may well find clear error even in a finding purportedly based on a credibility determination.

See also, United States v. *United States Gypsum Co.*, 333 U.S. at 396 ("[w]here such testimony is in conflict with contemporaneous documents we can give it little weight").*

CONCLUSION

For all the foregoing reasons, Critikon's conditional cross-petition for a writ of certiorari should be denied.

March 11, 1998

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* Critikon's reliance on the "sinister cast" language from *Inwood Lab., Inc.* v. *Ives Lab., Inc.*, 456 U.S. 844, 857-58, 102 S. Ct. 2182 (1982) is inapposite. The Court of Appeals was reversed in *Inwood* for making four separate *de novo* findings for which there was no support in the record. *Id.* at 856-57 n17-20.